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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/779,569

Applicant(s)

MALONEY ET AL.

Examiner

Ritesh Agrawal

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-103 is/are pending in the application.
- 4a) Of the above claim(s) 1-51, 61-63, 65-71, 76, 78-80, 101 and 102 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 52-60, 64, 72-75, 77, 81-100 and 103 is/are rejected.
- 7) ☒ Claim(s) 53-60 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>02/13/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Amendments

1. Applicant's election without traverse of Group II (claims 52-75, 77-100, and 103) in the reply filed on 09/15/06 is acknowledged. Furthermore, applicant's election of species A (claims 53-60), C (claim 64), and K (claim 77) is acknowledged.

Claims 1-51, 61-63, 65-71, 76, 78-80, and 101-102 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 09/15/06.

Claims 1-103 are pending, and claims 52-60, 64, 72-75, 77, 81-100, and 103 are under consideration.

Information Disclosure Statement

2. The Information Disclosure Statement filed 02/13/04 has been entered and considered. Initialed copies of the form PTO-1449 are enclosed with this action.

Drawings

3. The drawings are objected to because the drawings have not been placed in consecutive order (figure 6 appears before figure 4) and there doesn't appear to be any reason why figure 6 cannot be placed in proper numerical order (see 37 CFR 1.84(u)). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement

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drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The disclosure is objected to because of the following:

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

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The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

The abstract of the disclosure is objected to because the abstract is drawn to inventions for identifying medical literature using disease classification systems and genetic profiled. However, the elected invention is solely drawn to the use of genetic profiles. Correction is required. See MPEP § 608.01(b).

The use of the trademark MEDLINE has been noted in this application. It can be found, for example, on page 4 of the specification. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

It is noted that this example may not represent an exhaustive list of all trademarks present in the application. Applicant is required to thoroughly search the specification for any and all trademarks that may be present in the specification and modify them accordingly.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 52-60, 64, 72-74, 77, 81-100, and 103 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The following analysis of facts of this particular patent application follows the analysis suggested in the "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility"¹. Note that the text of the Guidelines is italicized.

To satisfy section 101 requirements, the claim must be for a practical application of the § 101 judicial exception, which can be identified in various ways (Guidelines, p. 19):

- The claimed invention "transforms" an article or physical object to a different state or thing.
- The claimed invention otherwise produces a useful, concrete and tangible result, based on the factors discussed below.

In the instant case, the claimed invention does not "transform" an article or physical object to a different state or thing because it merely searches databases to identify medical literature. This does not preclude the subject matter to be patentable as, for eligibility analysis, as

physical transformation "is not an invariable requirement, but merely one example of how a mathematical algorithm [or law of nature] may bring about a useful application." AT&T, 172 F.3d at 1358-59, 50 USPQ2d at 1452. If the examiner determines that the claim does not entail the transformation of an article, then the

¹ Available at http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/guidelines101_20051026.pdf

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examiner shall review the claim to determine if the claim provides a practical application that produces a useful, tangible and concrete result. In determining whether the claim is for a "practical application," the focus is not on whether the steps taken to achieve a particular result are useful, tangible and concrete, but rather that the final result achieved by the claimed invention is "useful, tangible and concrete." The claim must be examined to see if it includes anything more than a § 101 judicial exception. If the claim is directed to a practical application of the § 101 judicial exception producing a result tied to the physical world that does not preempt the judicial exception, then the claim meets the statutory requirement of 35 U.S.C. § 101. If the examiner does not find such a practical application, the examiner has determined that the claim is nonstatutory. (Guidelines, p. 20)

The question is thus whether the final result achieved by the claimed invention satisfies all three criteria of being useful, and concrete, and tangible.

Furthermore, the useful, tangible, and concrete result must be recited in the claim itself, rather than addressed in specification.

(2) **"TANGIBLE RESULT"** The tangible requirement does not necessarily mean that a claim must either be tied to a particular machine or apparatus or must operate to change articles or materials to a different state or thing. However, the tangible requirement does require that the claim must recite more than a § 101 judicial exception, in that the process claim must set forth a practical application of that § 101 judicial exception to produce a real-world result. The opposite meaning of "tangible" is "abstract."

The instant claims are drawn to computational means for searching databases to identify medical literature. However, as claimed, at least one embodiment of the method does not produce a tangible result. For example, the method as claimed may take place entirely within the confines of a computer or a human mind without any communication to the outside world and without using or making available for use, the results of the computation. Thus, the instant methods of the claims do not produce any tangible result.

Therefore, the final result achieved by the claimed invention does not satisfy all three criteria of being useful, and concrete, and tangible.

Furthermore, with respect to claim 103, the "code implementing a method" it is not clear that this represents computer-executable code, therefore it is being interpreted as non-functional descriptive material which is not statutory (see MPEP 2106.01).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 52-60, 64, 72-75, 77, 81-100, and 103 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The analysis is carried out with respect to the Wands factors of (a) the quantity of experimentation; (b) the amount of guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the predictability of the prior art; (g) the breadth of the claims; and (h) the relative skill in the art:

(a) The amount of experimentation required by the skilled artisan in order to practice the process of the claim would be unpredictable because:

(b) The claims require the ability to translate genetic profiles into identifiers for a medical literature classification system. However, applicant provides little guidance as to how to carry out this translation. The instant specification only suggests that the gene sequences (which only represent a subset of all genetic profile data) can somehow be mapped (or linked) to the identifiers using MEDLINE MESH trees (paragraph 51, lines 5-8). However, the specification provides no details as to how one would do this, nor does it explain how one could use the mapped (linked) information to actually carry out translation of the genetic profile data to the identifiers.

(c) The instant application provides no working examples for the translation of genetic profiles into identifiers for a medical literature classification system.

(d)-(f) The nature of the invention is some computational means by which to identify relevant medical literature based upon genetic profiles obtained from one or more patients. The method requires some method for translating the genetic profiles into identifiers of a medical literature classification system. The art suggests that bringing together such heterogeneous information "constitutes a real challenge" (IDS, Bodenreider et al., Proceedings of AMIA Annual Symposium, 2002, page 61, 1st column, 1st paragraph). Furthermore, the art suggests that while mapping (linking) information between data sources is necessary, it is insufficient for carrying out translations between the data sources (IDS, Cimino et al., Proc. Annu. Symp. Comp. Appl., page 731, 1st column, 2nd paragraph).

(g)-(h) The claims are broad and encompass the ability to translate any type of genetic profile data to identifiers in a medical literature classification system. While

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some methods of data translation are known in art, they need to be specifically applied and specially contoured for each type of data translation.

The skilled practitioner would first turn to the instant specification for guidance on how to translate genetic profile data into identifiers of a medical literature classification system. However, the specification provides little guidance as to how to do this. The guidance that is provided only covers a subset of the possible input data and only covers a subset of all steps that would need to be completed to carry out such a translation. As a result, the practitioner would then turn to the prior art, but the art suggests that such data integration remains a difficult problem. As a result, the practitioner would have to turn to their own experimentation to develop methodologies which the art suggest are difficult problems. Therefore the skilled practitioner would be subject to the burden of undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 52-60, 64, 72-75, 77, 81-100, and 103 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 52 recites a step of "filtering the medical literature database based at least on relevance to evidence-based medicine" in line 6-7. It is unclear as to how this related to the rest of the method. Does the filtering create a smaller database that is then searched by the identifiers? Does the filtering filter the hits received by searching the full

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database with the identifiers? Furthermore, it is unclear as to how one determines the relevance of a database to evidence-based medicine.

Claim 52 recites the step of "identifying one or more literature articles from the medical literature database based at least on the one or more identifiers of the medical literature classification system" in lines 8-10. If the identification of articles need only be based upon the identifiers, it is unclear what purpose the filtering step serves as it appears that it need not play a role in the identification of articles.

Claim 53 recites the phrase "genetic profiles includes one or more partial genetic codes." It is unclear to what a "partial genetic code" refers. Applicant has not defined a genetic code and in the art a genetic code is defined as the code by which a cell translates codons into amino acids. It is unclear what a partial fraction of this would represent.

The term "generic" in claim 77 is a relative term which renders the claim indefinite. The term "generic" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear how a "generic" filter contrasts with a non-generic filter. Applicant provides no definition for the term "generic" only providing an intended use therefore (specification, paragraph 58).

Claim 81 recites the phrase "when used with a gold standard set of citations." It is unclear as to what the phrase "when used with" refers. It is unclear what is being used with the gold standard set of citations. Does this refer to the method as a whole? Does it

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refer to just the filtering step? Does it refer to a second database that is used along with the originally searched database?

The term "gold standard" in claim 81 is a relative term which renders the claim indefinite. The term "gold standard" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear what is required for a citation to be part of the "gold standard" set of citations.

Claim 83 recites the phrase "evidence based medicine articles" in line 1. It is unclear as to whether these articles are the same or different from the "evidence based medicine articles" of claim 81.

Claims 84-89 recite the limitation "the method of claim 81, wherein high specificity" in line 1. There is insufficient antecedent basis for this limitation in the claim. There is no reference to specificity in claim 81.

Claims 90-97 recite the limitation "the method of claim 81, wherein high sensitivity" in line 1. There is insufficient antecedent basis for this limitation in the claim. There is no reference to sensitivity in claim 81.

The term "gold standard" in claim 98 is a relative term which renders the claim indefinite. The term "gold standard" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear what is required for a citation to be part of the "gold standard" set of citations.

Claim 100 recites the phrase "physical findings." It is unclear as to what the phrase refers and no definition is provided.

Claim 103 recites a step of "filtering the medical literature database based at least on relevance to evidence-based medicine" in line 5-6. It is unclear as to how this related to the rest of the method. Does the filtering create a smaller database that is then searched by the identifiers? Does the filtering filter the hits received by searching the full database with the identifiers? Furthermore, it is unclear as to how one determines the relevance of a database to evidence-based medicine.

Claim 103 recites the step of "identifying one or more literature articles from the medical literature database based at least on the one or more identifiers of the medical literature classification system" in lines 7-9. If the identification of articles need only be based upon the identifiers, it is unclear what purpose the filtering step serves as it appears that it need not play a role in the identification of articles.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 52-58 72-75, 77, 100, and 103 are rejected under 35 U.S.C. 102(b) as being anticipated by Rappaport (U.S. Publication # 2002/0007285) published January 17th, 2002.

The claims are drawn to a method performed by a computer comprising:

- (a) receiving one or more genetic profiles
- (b) translating the profiles into identifiers of a medical literature database
- (c) filtering the medical literature database based on evidence-based medicine
- (d) identifying one or more medical literature articles from the database

Rappaport discloses a method for use on a computer (paragraph 63, lines 7-10) on computer readable medium (paragraph 21, lines 1-3) for receiving laboratory test results from a patient (for example, paragraph 5, figure 11) wherein the laboratory results may include genetic profile data (paragraph 32, lines 6-9). These results are associated with a code (paragraph 6, line 4) wherein the results in combination with the code are translated in concepts and contexts (for example, paragraph 79) that are used for identifying associated information that may include medical literature articles (for example, paragraph 105). Since the database of information being searched is a database of evidence based medicine resources (for example, module 1017, figure 10; paragraph 21, lines 19-21) the retrieved articles are filtered based on a relevance to evidence-based medicine.

With respect to claims 53-58 including partial or full information, Rappaport discloses obtaining genetic, genomic, and proteomic data as part of his laboratory tests (paragraph 32, lines 6-9). The tests would result in the production of full and partial genetic, genomic, and sequence information.

With respect to claim 72, Rappaport discloses that the documents present in the evidence based medicine database include clinical information in the form of related information on diagnoses and procedures (paragraph 196).

With respect to claim 73, since the database being searched is a evidence-based medicine database (as cited above) the articles retrieved would be evidence-based articles.

With respect to claim 74, Rappaport discloses that the information provided from the database can include the results of randomized trials (a treatment that has been validated) as well as suggestions as to whether or not a procedure or test should be performed (see paragraph 21).

With respect to claim 75, Rappaport discloses making the identified articles available to the provider (for example, see paragraph 22).

With respect to claim 77, and in light of the indefiniteness of the term (as discussed above) since Rappaport is using evidence-based medicine to create a specialized database (as cited above) from which to carry out searches, it is a "generic" filter.

With respect to claim 100, Rappaport discloses that ability to search using physical condition information (for example, pregnancy, see paragraph 100) which is a physical finding.

With respect to claim 103, it drawn to the method of claim 52 on a computer readable medium which Rappaport discloses (as cited above).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 59-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rappaport (U.S. Publication # 2002/0007285) as applied to claims 52-58 72-75, 77,

100, and 103 above, and further in view of Davies et al. (U.S. Patent Publication # 2003/0046114) filed October 23rd, 2001.

The claims are drawn to the method of claim 52 wherein the genetic profiles include single nucleotide polymorphism identifiers (claim 59) and haplotype identifiers (claim 60).

Rappaport discloses the method of claim 52 (as cited above), but does not disclose genetic profiles including single nucleotide polymorphism or haplotype information.

Davies et al. disclose patient profiles including single nucleotide polymorphism information and haplotype information (for example, paragraph 19; paragraph 68).

It would have been obvious, to one of ordinary skill in the art, at the time the invention was made, to include the polymorphism and haplotype information of Davies et al. in the method of Rappaport. One of ordinary skill in the art would have been motivated to do this because the goal of the method of Rappaport is to improve patient care by improving awareness of medical literature. Davies et al. disclose that inclusion of haplotype information and polymorphism information can aide patient care (for example, paragraph 26, lines 9-13), thus furthering the goal of Rappaport.

Claim Objections

10. Claims 53-60 are objected to because of the following informalities:

The claims recite the phrase "one or more genetic profiles includes" in line 1. The term "includes" should be in the singular form. Appropriate correction is required.

Conclusion

11. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ritesh Agrawal whose telephone number is (571) 272-2906. The examiner can normally be reached on 8:30 AM - 5:00 PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ritesh Agrawal, PhD *RA*

[Signature] 02/16/07
SHUBO (JOE) ZHOU, PH.D.
PATENT EXAMINER